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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,948	06/20/2003	Richard Mark Amasino	960296.96871	9478
7590 Nicholas J. Seay P O Box 2113 Madison, WI 53701-2113	01/04/2007		EXAMINER MEHTA, ASHWIN D	ART UNIT PAPER NUMBER 1638

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/600,948	AMASINO ET AL.	
	Examiner	Art Unit	
	Ashwin Mehta	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 07 November 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 21-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 21-30 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 20 June 2003 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II, claims 6-11 and 14-18 in the reply filed on August 11, 2006, and nucleotide sequences encoding the amino acid sequence of SEQ ID NO: 4 in the paper filed November 7, 2006 is acknowledged. The traversal is on the ground(s) that the subject matter of Groups I-II, relating to FLC family members involved in altering flowering time, are intimately related (response filed August 11, 2006, page 7, 3rd full paragraph, and response filed November 7, 2006, page 4, 3rd full paragraph). The restriction requirement mailed June 23, 2006 indicated that Group I was drawn towards transgenic plants comprising an FLC gene family member, wherein the plant has early flowering time, and that Group II encompassed transgenic plants which expressed an FLC family member in antisense orientation, wherein the plant has delayed flowering. However, the specification, as discussed below, teaches that transgenic *Arabidopsis* plants overexpressing FLC2 (SEQ ID NO: 4) are delayed in flowering, while *flc2* mutants, which do not express SEQ ID NO: 4, display early flowering. As this is opposite to what the restriction requirement indicated, the restriction between Groups I and II is hereby withdrawn. In view of the withdrawal of the restriction requirement regarding Groups I and II, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re*

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Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

However, the requirement to select a nucleotide sequence for examination is still deemed proper, and is therefore made FINAL.

In the response to the restriction requirement filed August 11, 2006 Applicants indicated that, to clarify the claim scope of this divisional application from claims issued in the parent, claims 6-11 and 14-18 were being “withdrawn” in favor of new claims 21-30, which also read on Group II (page 7, 2nd full paragraph). However, because claims 6-11 and 14-18 were still pending, and they read on the elected group, the Examiner could not simply disregard them. That is, claims 6-11 and 14-18 would also have to have been examined. However, claims 6-11 and 14-18 still encompassed multiple sequences, and Applicants did not also select a nucleotide sequence for examination, as required in the restriction requirement mailed June 23, 2006. Therefore a notice of non-compliance was mailed on October 31, 2006, which indicated that claims 6-11 and 14-18 were still pending and a nucleotide sequence was not elected. Applicants filed a paper on November 7, 2006, which indicated the nucleotide sequence encoding SEQ ID NO: 4 was elected, and that claims 6-11 and 14-18 were being cancelled “at the request of the Examiner”, in favor of new claims 21-30 (page 4, 1st full paragraph). The Examiner did not “request” that these claim amendments be made. After receiving the non-compliant letter, Applicants’ representative called the Examiner for clarification, and inquired whether cancellation of claims 6-11 and 14-18 would obviate the issue. The Examiner replied in the affirmative, but did not “request” that the claims be cancelled, as alleged in the paper filed November 7, 2006. The confusion seems to have arisen due to Applicants’ labeling of claims 6-11 and 14-18 as “withdrawn”, even though Applicants elected the group comprising them in

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response to the restriction requirement. The labelling of these claims by Applicants as "withdrawn", even though they were part of the elected group, was not proper.

Claims 21-30 and nucleotide sequences encoding SEQ ID NO: 4 are examined in this Office action.

Specification

2. The statement on page 1 of the specification claiming priority benefit to application 09/513,775 should be amended to recite the U.S. patent number that it issued as.
3. Page 1 of the specification recites the statement, "To be determined." Clarification of this statement is required. New matter must be avoided.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 27 and 28 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 27 is directed to a genetic construction. The specification does not provide a definition for "genetic construction." As broadly interpreted, a gene naturally occurring within the genome of a plant can be considered a "genetic construction." Claim 28 is drawn to a plant comprising the genetic construction of claim 27. These products read on products of nature and thus, are unpatentable. See *American Wood v. Fiber Disintegrating Co.*, 90 U.S. 566 (1974),

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American Fruit Growers v. Brodex Co., 283 U.S. 2 (1931), *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 33 U.S. 127 (1948), *Diamond v. Chakrabarty*, 206 USPQ 193 (1980). It is suggested that claim 27 be amended to indicate that it is recombinant, or otherwise required the hand of man for its production. Note: such an amendment would also make claim 28 identical in scope to claim 29. When two claims are identical in scope, despite a difference in wording, when they are found allowable, one claim will be objected to under 37 CFR 1.75.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 21-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 21, 23, 27, 29, and 30: the recitation, “FLC2” or “Flowering Locus C2” renders the claims indefinite. The specification indicates that FLC proteins have a MADS box domain, repress flowering, and plants having a dominant FLC allele require vernalization for flowering (pages 3-4). However, it is unclear what distinguishes FLC2 from FLC1 or FLC3, which is important since the claims clearly recite that the transgene or protein coding region is for an FLC2 protein. Further, claims 23, 27, 29, and 30 encompass protein coding regions for FLC2 proteins that have at least 50% identity to SEQ ID NO: 4 outside of the MADS box domain. However, the specification indicates that *Arabidopsis* FLC1 has 50% identity with FLC2 (SEQ ID NO: 4) outside of the MADS box domain. It is unclear, therefore, whether FLC1 is

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encompassed by "FLC2". If not, it is unclear how to distinguish FLC1 from the protein coding regions encompassed by the claims.

In claim 22: the claim is indefinite because it is unclear if the seed comprises the transgene. It is suggested that the recitation, --, wherein the seed comprises said transgene-- be inserted at the end of the claim.

In claim 25: the recitation, "the sequence" in line 2 renders it indefinite. It is unclear if the recitation is referring to the "isolated nucleotide sequence", or the "coding sequence" recited in line 1.

In claim 26: the recitation, "the sequence" in line 2 renders the claim indefinite. It is unclear the recitation is referring to the "isolated DNA sequence" or "a DNA sequence" recited in line 1. Further, the recitation in line 2 attempting to further define one of the DNA sequences recited in line 1, by indicating it is defined by SEQ ID NO: 4. However, SEQ ID NO: 4 is an amino acid sequence. It is suggested that "the sequence", recited in line 2, be replaced with --the protein--.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 21-24 and 27-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

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relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification indicates that the *Arabidopsis FLC1* cDNA sequence, which encodes Flowering Locus C1, a MADS box protein involved in flowering regulation, was used to identify two other MADS box genes, one of which is *FLC2* (page 24; SEQ ID NO: 3). The amino acid sequence encoded by *FLC2* is set forth in SEQ ID NO: 4. The specification indicates that late-flowering varieties of *Arabidopsis* contain dominant alleles of *FLC* and *FRI* (*Frigida*), which suppress flowering. Vernalization of these late-flowering varieties can suppress the late-flowering phenotype. *FLC* and *FRI* can be regarded as genes that create a requirement for vernalization (pages 3-4). The specification indicates that *flc2* mutant *Arabidopsis* plants, which contain a T-DNA genomic insertion, flower earlier than wild-type plants. Overexpression of *FLC2* in transgenic *Arabidopsis* plants delayed flowering and formed two to three times the number of leaves before flowering (pages 25-26).

Claim 21 encompasses a broad genus: any transgenic plant comprising in its genome any *FLC2* gene, wherein expression causes a delay in the onset of flowering. Claim 23 is drawn towards any seed of any transgenic plant of any species, wherein the seed comprises in its genome a transgene comprising a plant expressible promoter and an antisense coding region complementary to a protein coding region for any plant *FLC2* protein, the protein (i) having a MADS box domain, (ii) being at least 50% identical to SEQ ID NO: 4 outside the MADS box domain, and (iii) effective when expressed in transgenic plants to cause a delay in the onset of flowering. Claim 24 is drawn to a plant grown from the seed of claim 23. Claim 27 is drawn to any genetic construction comprising a plant expressible promoter operably linked a protein

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coding sequence for a plant FLC2 protein (i) having a MADS box domain, (ii) being at least 50% identical to SEQ ID NO: 4 outside the MADS box domain, and (iii) effective when expressed in transgenic plants to cause a delay in the onset of flowering. Claim 28 is drawn towards a plant comprising said construction. Claim 29 is directed to a transgenic plant comprising a transgene encoding a FLC2 protein as recited above. Claim 30 is directed to a method of producing a transgenic plant with altered flowering characteristics, comprising contacting a plant cell with a transgene comprising a plant expressible promoter and a protein coding sequence encoding a plant FLC2 as recited above, regenerating a transgenic plant, wherein the plant exhibits 10% more leaves than a non-transgenic plant of the same genetic background.

The specification indicates on pages 7 and 24 that FLC1 and FLC2 from *Arabidopsis* are 60% identical over their entire length and over 50% identical over their entire region outside of the MADS box domain. However, this compares FLC2 to FLC1. The specification does not describe protein coding regions for FLC2 proteins, other than SEQ ID NO: 4, including those that differ from SEQ ID NO: 4 by as much as 50% outside of the MADS box domain (which is defined in the specification on page 7 as the first 60 amino acids) and which delay flowering. FLC1 proteins are apparently distinct from FLC1, as they are separated in the phylogenetic tree presented in Figure 1, and given that the specification indicates that *Brassica* FLC1 homologs have greater identity to *Arabidopsis* FLC1, than FLC1 does to FLC2, outside of the MADS box domain (page 7). The specification does not describe a single species nucleotide sequences encoding an FLC2 protein that differs by as much as 50% from SEQ ID NO: 4 outside of the MADS box. The specification does not describe other domains within SEQ ID NO: 4 that are required for functionality and which would be shared by other species encompassed by the

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claims. Given the breadth of the claims and the lack of written description as discussed above, the specification fails to provide an adequate written description of the multitude of nucleotide sequences encompassed by the claims.

7. Claims 21-24 and 27-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed seeds, plants, construction, and method wherein the protein coding sequence encodes SEQ ID NO: 4, does not reasonably provide enablement for the claimed invention wherein the encoded FLC2 differs from SEQ ID NO: 4 by as much as 50% outside of the MADS box domain. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

As discussed above, the specification teaches that transgenic expression of SEQ ID NO: 4 in *Arabidopsis* results in delayed flowering, and two to three times the number of leaves, compared to wild-type plants. However, while the specification compares the sequence identity of the *Arabidopsis* FLC1 with *Brassica* FLC1 homologs and *Arabidopsis* FLC2 and FLC3, it does not teach other FLC2 coding sequences. No teaching is provided concerning active site residues or other domains of SEQ ID NO: 4 that are essential for its function. The specification also does not provide any teaching as to what kind of changes that can be made to SEQ ID NO: 4 without affecting its function. In the absence of this guidance it would require undue experimentation for one skilled to produce all of the nucleic acid sequences that encode amino acid sequences that differ from SEQ ID NO: 4 outsides of the MADS box, without altering its functional activity. See In re Bell, 26 USPQ2d 1529, 1532 (Fed. Cir. 1993) and In re Deuel, 34

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UPSQ2d, 1210 (Fed. Cir. 1995), which teach that the mere existence of a protein does not enable claims drawn to a nucleic acid encoding that protein. See also Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016 at 1021 and 1027, (Fed. Cir. 1991) at page 1021, where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence), and at page 1027, where it is taught that the disclosure of a few gene sequences did not enable claims broadly drawn to any analog thereof. Given the breadth of the claims, unpredictability of the art and lack of guidance of the specification as discussed above, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

8. Claims 21-30 are rejected.

Contact Information

Any inquiry concerning this or earlier communications from the Examiner should be directed to Ashwin Mehta, whose telephone number is 571-272-0803. The Examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anne Marie Grunberg, can be reached at 571-272-0975. The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as

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December 20, 2006



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Art Unit 1638